UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

BIOVAIL LABORATORIES INTERNATIONAL SRL, Plaintiff, vs. PADDOCK LABORATORIES, INC., Defendant.	C.A No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biovail Laboratories International SRL ("Biovail") for its Complaint against Paddock Laboratories, Inc. ("Paddock"), to the best of its knowledge, information, and belief, alleges:

PARTIES

1. Plaintiff Biovail is an international society with restricted liability organized and existing under the laws of Barbados having a principal place of business at Welches, Christ Church, Barbados, West Indies.

2. Upon information and belief, Defendant Paddock is a Minnesota corporation having a principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271, and 28 U.S.C. §§ 2201 and 2202.

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Paddock by virtue of its incorporation in Minnesota.

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and § 1400(b).

7. An actual, substantial, and justiciable controversy exists between Biovail and Paddock as to the infringement and validity of United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,563,823, 7,553,992, and 7,671,094.

PATENTS IN SUIT

8. Biovail is the lawful owner by assignment of exclusive rights to United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,563,823, 7,553,992, and 7,671,094, including all right to sue and recover for infringement.

9. United States Patent No. 7,569,610 ("'610 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued August 4, 2009, naming Werner Oberegger, Paul Maes, and Mohammad Ashty Saleh as inventors. The '610 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '610 patent is attached as Exhibit A.

10. United States Patent No. 7,572,935 ("'935 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued August 11, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '935 patent is a continuation of Application No. 11/751,768, filed on May 22, 2007, which is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '935 patent is attached as Exhibit B.

11. United States Patent No. 7,649,019 ("'019 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued January 19, 2010, naming Werner Oberegger, Fang Zhou, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '019 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '019 patent is attached as Exhibit C.

12. United States Patent No. 7,563,823 ("'823 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued June 21, 2009, naming Werner Oberegger, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '823 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '823 patent is attached as Exhibit D.

13. United States Patent No. 7,553,992 ("'992 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued June 30, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '992 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '992 patent is attached as Exhibit E.

14. United States Patent No. 7,671,094 ("'094 patent"), entitled "Bupropion Hydrobromide and Therapeutic Applications," duly and legally issued March 2, 2010, naming Robert Perry Williams and Peter Harris Silverstone as inventors. The '094 patent is a continuation-in-part of Application No. 11/751,768, filed May 22, 2007, now United States Patent No. 7,569,610; and a continuation-in-part of Application No. 11/755,946 filed on May 31, 2007, now United States Patent No. 7,553,992, both of which are continuations of Application No. 11/475,252, filed Jun. 27, 2006, now United States Patent No. 7,241,805. A copy of the '094 patent is attached as Exhibit F.

APLENZIN™ ER

15. Biovail is the holder of New Drug Application ("NDA") No. 22-108 for Aplenzin™ (bupropion hydrobromide) ER Tablets, 174 mg, 348 mg, and 522 mg.

16. On April 23, 2008, the U.S. Food and Drug Administration ("FDA") approved NDA No. 22-108 for the manufacture, marketing, and sale of a product containing the drug bupropion hydrobromide for treatment of depression. The drug bupropion hydrobromide with the trademark Aplenzin™ ER has been sold under NDA 22-108 since approval.

17. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the ’935, ’019, and ’094 patent claims cover Aplenzin™ ER. The ’935, ’019, and ’094 patents are accordingly listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”). The ’610 patent is also listed in the Orange Book covering methods of using Aplenzin™ ER.

PADDOCK’S ANDA

18. Upon information and belief, Paddock submitted Abbreviated New Drug Application No. 20-1332 (“ANDA”) to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in commercial manufacture, use, and/or sale of bupropion hydrobromide extended-release tablets (“Paddock’s Generic Product”), a generic version of Aplenzin™ ER, before expiration of the ’610, ’935, ’019, ’823, ’992, and ’094 patents. Paddock’s ANDA currently includes three dosage forms of Paddock’s Generic Product, 174 mg, 348 mg, and 522 mg.

19. Upon information and belief, Paddock’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging at least the ’610, ’935, ’019, and ’094 patents listed in the FDA’s Orange Book as covering Aplenzin™ ER and its use are invalid and/or will not be infringed by commercial manufacture, use, or sale of Paddock’s Generic Product.

20. On January 25, 2010, Biovail received written notification of ANDA No. 20-1332 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 314.95 (“Paragraph IV letter”). Approximately a month later, Biovail received Paddock’s second Paragraph IV letter. The stated purpose of the letters was to notify Biovail that Paddock filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 20-1332 for approval to commercially manufacture and sell Paddock’s Generic Product before the expiration of several of Biovail’s Orange Book listed patents covering Aplenzin™ ER and its use. The Paragraph IV letters allege that those Biovail patents are invalid, unenforceable, and/or will not be infringed by commercial manufacture, use, or sale of Paddock’s Generic Product.

21. Biovail commenced its first action March 9, 2010 within 45 days of receiving Paddock's first two Paragraph IV letters. That case is currently pending in this court (C.A. No. 10-cv-00687-MJD-JJK).

22. Biovail received Paddock's third Paragraph IV letter on April 7, 2010. The stated purpose of this letter was to notify Biovail that Paddock filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 20-1332 for approval to commercially manufacture and sell Paddock's Generic Product before the expiration date of the '094 patent. The Paragraph IV letters allege Biovail's patents listed in the Orange Book covering Aplenzin™ ER and its use are invalid, unenforceable, and/or will not be infringed by commercial manufacture, use, or sale of Paddock's Generic Product.

23. Biovail commenced this action within 45 days of receiving Paddock's third Paragraph IV letter.

24. This action is being filed in light of Paddock's multiple Paragraph IV certifications.

COUNT I
(Infringement of the '610 Patent Under 35 U.S.C. § 271(e)(2))

25. Biovail incorporates paragraphs 1-24.

26. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '610 patent before its expiration, Paddock has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT II
(Declaratory Judgment of Infringement of the '610 Patent Under 35 U.S.C. § 271(a)-(c))

27. Biovail incorporates paragraphs 1-26.

28. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

29. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for

declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

30. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA No. 20-1332, to begin manufacturing, marketing, offering to sell, or selling within the United States Paddock's Generic Product with a product insert directing physicians and patients in the use of Paddock's Generic Product.

31. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or selling within the United States, and/or import into the United States Paddock's Generic Product before expiration of the '610 patent.

32. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '610 patent.

33. Paddock's actions, including without limitation the filing of ANDA No. 20-1332, exhibit a refusal to change the course of its action despite Biovail's patent rights.

34. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '610 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '610 patent.

35. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '610 patent by Paddock or its agents, will infringe the '610 patent.

COUNT III
(Infringement of the '935 Patent Under 35 U.S.C. § 271(e)(2))

36. Biovail incorporates paragraphs 1-35.

37. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the ’935 patent before its expiration, Paddock has infringed the ’935 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT IV
(Declaratory Judgment of Infringement of the ’935 Patent Under 35 U.S.C. § 271(a)-(c))

38. Biovail incorporates paragraphs 1-37.

39. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

40. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail’s request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

41. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA No. 20-1332, to begin manufacturing, marketing, offering to sell, or selling within the United States Paddock’s Generic Product with a product insert directing physicians and patients in the use of Paddock’s Generic Product.

42. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Paddock’s Generic Product before expiration of the ’935 patent.

43. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock’s Generic Product before expiration of the ’935 patent.

44. Paddock’s actions, including without limitation the filing of ANDA No. 20-1332, exhibit a refusal to change the course of its action despite Biovail’s patent rights.

45. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '935 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '935 patent.

46. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '935 patent by Paddock or its agents, will infringe the '935 patent.

COUNT V
(Infringement of the '019 Patent Under 35 U.S.C. § 271(e)(2))

47. Biovail incorporates paragraphs 1-46.

48. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '019 patent before its expiration, Paddock has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VI
(Declaratory Judgment of Infringement of the '019 Patent Under 35 U.S.C. § 271(a)-(c))

49. Biovail incorporates paragraphs 1-48.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

51. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

52. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA No. 20-1332, to begin manufacturing, marketing, offering to sell, or

selling within the United States Paddock's Generic Product with a product insert directing physicians and patients in the use of Paddock's Generic Product.

53. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Paddock's Generic Product before expiration of the '019 patent.

54. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '019 patent.

55. Paddock's actions, including without limitation the filing of ANDA No. 20-1332, exhibit a refusal to change the course of its action despite Biovail's patent rights.

56. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '019 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '019 patent.

57. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '019 patent by Paddock or its agents, will infringe the '019 patent.

COUNT VII
(Infringement of the '823 Patent Under 35 U.S.C. § 271(e)(2))

58. Biovail incorporates paragraphs 1-57.

59. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '823 patent before its expiration, Paddock has infringed the '823 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VIII

(Declaratory Judgment of Infringement of the ’823 Patent Under 35 U.S.C. § 271(a)-(c))

60. Biovail incorporates paragraphs 1-59.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

62. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail’s request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

63. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA No. 20-1332, to begin manufacturing, marketing, offering to sell, or selling within the United States Paddock’s Generic Product with a product insert directing physicians and patients in the use of Paddock’s Generic Product.

64. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Paddock’s Generic Product before expiration of the ’823 patent.

65. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock’s Generic Product before expiration of the ’823 patent.

66. Paddock’s actions, including without limitation the filing of ANDA No. 20-1332, exhibit a refusal to change the course of its action despite Biovail’s patent rights.

67. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock’s Generic Product before expiration of the ’823 patent, and the active inducement of and/or contribution to any of those activities, will infringe the ’823 patent.

68. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '823 patent by Paddock or its agents, will infringe the '823 patent.

COUNT IX
(Infringement of the '992 Patent Under 35 U.S.C. § 271(e)(2))

69. Biovail incorporates paragraphs 1-68.

70. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '992 patent before its expiration, Paddock has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT X
(Declaratory Judgment of Infringement of the '992 Patent Under 35 U.S.C. § 271(a)-(c))

71. Biovail incorporates paragraphs 1-70.

72. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

73. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

74. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA No. 20-1332, to begin manufacturing, marketing, offering to sell, or selling within the United States Paddock's Generic Product with a product insert directing physicians and patients in the use of Paddock's Generic Product.

75. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell

within the United States, and/or import into the United States Paddock's Generic Product before expiration of the '992 patent.

76. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '992 patent.

77. Paddock's actions, including without limitation the filing of ANDA No. 20-1332, exhibit a refusal to change the course of its action despite Biovail's patent rights.

78. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '992 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '992 patent.

79. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '992 patent by Paddock or its agents, will infringe the '992 patent.

COUNT XI
(Infringement of the'094 Patents Under 35 U.S.C. § 271(e)(2))

80. Biovail incorporates paragraphs 1-79.

81. By seeking approval of its ANDA No. 20-1332 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '094 patent before its expiration, Paddock has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT XII
(Declaratory Judgment of Infringement of the '094 Patent Under 35 U.S.C. § 271(a)-(c))

82. Biovail incorporates paragraphs 1-81.

83. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

84. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

85. Upon information and belief, Paddock intends, soon after the FDA has approved its ANDA 20-1332, to begin manufacturing, marketing, offering to sell, or selling within the United States Paddock's Generic Product with a product insert directing physicians and patients in the use of Paddock's Generic Product.

86. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Paddock's Generic Product before expiration of the '094 patent.

87. Upon information and belief, Paddock has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '094 patent.

88. Paddock's actions, including without limitation the filing of ANDA No. 20-332, exhibit a refusal to change the course of its action despite Biovail's patent rights.

89. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product before expiration of the '094 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '094 patent.

90. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Paddock's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States,

and/or importation into the United States of Paddock's Generic Product before expiration of the '094 patent by Paddock or its agents, will infringe the '094 patent.

INJUNCTIVE RELIEF

91. Biovail will be substantially and irreparably damaged and harmed by Paddock's infringing activities unless those activities are enjoined by this Court. Biovail does not have an adequate remedy at law.

PRAYER FOR RELIEF

Because Paddock has submitted multiple Paragraph IV certifications for bupropion hydrobromide, including a certification submitted after Biovail's earlier complaint (C.A. No. 10-cv-00687-MJD-JJK), Biovail respectfully prays for the following relief:

a. An order consolidating Biovail's earlier complaint (C.A. No. 10-cv-00687-MJD-JJK) with this action.

b. A judgment that Paddock has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '610 patent.

c. A judgment that Paddock has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '935 patent.

d. A judgment that Paddock has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '019 patent.

e. A judgment that Paddock has infringed the '823 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for

commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '823 patent.

f. A judgment that Paddock has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '992 patent.

g. A judgment that Paddock has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-1332 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Paddock's Generic Product before expiration of the '094 patent.

h. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the '610 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '610 patent.

i. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the '935 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '935 patent.

j. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the '019 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '019 patent.

k. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the '823 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock's

Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the ’823 patent.

l. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the ’992 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock’s Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the ’992 patent.

m. A declaration issued under 28 U.S.C. § 2201 that Paddock would infringe one or more claims of the ’094 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Paddock’s Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the ’094 patent.

n. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 20-1332, if any, shall be no earlier than the date of expiration of any patent-in-suit Paddock is found to infringe, including any extensions.

o. An injunction issued under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Paddock, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offers to sell, or sale within the United States, or importation into the United States, of Paddock’s Generic Product or products not colorably different from Paddock’s Generic Product before the date of expiration of any patent-in-suit Paddock is found to infringe, including any extensions.

p. A declaration that Paddock has no legal or equitable defense to Biovail’s allegations of infringement.

q. An award declaring this case exceptional under 35 U.S.C. § 285 and granting Biovail its attorneys’ fees.

r. An award of Biovail’s costs and expenses in this action.

s. An award of damages or other monetary relief to Biovail under 35 U.S.C. § 271(e)(4)(C), including by an accounting, as appropriate.

t. An award of any further and additional relief as this Court may deem just and proper.

Dated: April 15, 2010

By: s/ Calvin L. Litsey

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